NDA 19-269/S-016

SEP 18 1998

Glaxo Wellcome Inc.
Five Moore Drive
P.O.Box 13358
Research Triangle Park, North Carolina 27709

Attention: John W. Morgan, Ph.D.
Associate Director, Regulatory Affairs

Dear Dr. Morgan:

Please refer to your supplemental new drug application dated May 13, 1998, received May 14, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ventolin (albuterol sulfate) Inhalation Solution, 0.5%.

Reference is also made to your September 11, 1998, telephone conversation with Ms. Parinda Jani of this Division.

The supplement provides for a revised ADVERSE REACTIONS section. The sentence "Rare cases of supraventricular tachycardia, urticaria, angioedema, rash, bronchospasm, and oropharyngeal edema have been reported after the use of inhaled albuterol." has been changed to "Cases of urticaria, angioedema, rash, bronchospasm, hoarseness, oropharyngeal edema, and arrhythmias (including atria1 fibrillation, supraventricular tachycardia, extrasystoles) have been reported after the use of VENTOLIN Inhalation Solution."

In addition, the "Rx only" statement has been added according to Procedural Guidance #3, Implementation of Section 126, Elimination of Certain Labeling Requirements, of the Food and Drug Modernization Act of 1997, issued in February 1998.

We note that the changes were put into effect per 21 CFR 314.70(c)(2)(i).

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

As you agreed, the following changes will be made in the package insert at the next printing or 6 months, whichever occurs first.

> Under DOSAGE AND ADMINISTRATION section, the first sentence under "The dosage for Adults and Children Over 12 Years of Age" will be revised from "The usual dosage for adults and children 12 year of age and older is...." to "The usual

dosage for adults and children over 12 years of age is...” A similar change will be incorporated in Patient’s Instruction for Use leaflet, item #1.

The changes may be reported in the annual report.

Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

Should a letter communicating important information about this drug product (i.e., a “Dear Doctor” letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857-9787

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Ms. Parinda Project Manager, at (301) 827-1064.

Sincerely yours,

John K. Jenkins, M.D., F.C.C.P.
Director
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research